

**Summary of the
Third Interim Meeting of the
National Environmental Laboratory Accreditation Conference
January 12-16, 1998**

OPENING PLENARY SESSION

The Third Interim Meeting of the National Environmental Laboratory Accreditation Conference (NELAC) was opened by Ms. Jeanne Mourrain, NELAC Director on Monday, January 12, 1998, at the Sheraton National Hotel in Arlington, VA. There were approximately 250 registrants. This included 9 representatives of local or county government, 61 representatives of State government, 51 representatives of EPA's Headquarters programs and Regional offices, and 16 representatives of other Federal government organizations. In the private sector, there were 37 representatives from environmental testing laboratories, 6 representatives from laboratory accreditation organizations, and 19 from industry. Other groups attending included consultants, academia, and environmental interest groups.

In the opening plenary session, Ms. Mourrain welcomed the participants of the Third NELAC Interim Meeting. She made special note of three items for this meeting. First, the Field Measurements Committee will be proposed as a standing committee in the next Annual Meeting. Second, she mentioned that last July, a personnel section of Chapter 4 did not pass in its entirety; this section has been revised and scrutinized by the Accreditation Process Committee. Third, there will be an ELAB open forum, which will provide a chance for participants to meet informally and talk with ELAB members.

Ms. Mourrain then recognized Mr. Ted Coopwood, who recently accepted a new position in EPA, for his contributions and devotion to NELAC. Mr. Bruce Harvey, of RTI, made a presentation to Mr. Coopwood stating that he will be missed.

Ms. Carol Batterton, NELAC Chair, stated that although the final decision making occurs at the Annual Meetings, this Interim Meeting is a good opportunity for people to provide input to the committees. Different opinions should be expressed--the experience is needed. It is the committees' job to deliberate on these ideas and develop recommendations for changes to the Standards to be presented at the Annual Meeting. Ms. Batterton re-emphasized the importance of the Interim Meeting for hearing everyone's opinions and advised patience as we address the details of the implementation phase. She remarked that we already have a good set of standards, and charged the participants to do their best to make them better. Ms. Batterton announced that 25 States had already announced their intent for NELAC accreditation, and they may be approved in 1998. She announced that the next Annual Meeting will be at the Omni Hotel in San Antonio, Texas.

Mr. Peter Preuss, Director of EPA ORD's National Center of Environmental Research and Quality Assurance (NCERQA), was the keynote speaker. EPA'S National Environmental Laboratory Accreditation Program is now located in the Quality Assurance Division in NCERQA. He offered congratulations to participants on the magnitude of NELAC's accomplishments. He attributed much of that success to the working partnership among the States, EPA, and the

private sector. He assured NELAC of continued and enhanced support from EPA's Office of Research and Development, stating that they will remain a principal player in the accreditation of environmental laboratories. Mr. Preuss commented that the "quality of science" issue is a focal point. Major issues being addressed by EPA include quality assurance and oversight of peer review. He stated that senior management at EPA gives strong support for NELAC. Mr. Preuss acknowledged that funding is tight at both the State and industry level, but remarked that with the challenge of implementation ahead, there is much work to do. He encouraged all States to participate in NELAP, in order to establish a truly national program. Mr. Preuss reminded conference participants that there would be an open meeting with the National Institute of Standards and Technology and encouraged attendance. In addition, he emphasized the role of EPA Regions in the implementation phase of NELAP--the Regions will be key to involvement of the States.

Mr. Preuss announced that Dr. James Stemmler would replace Mr. Ted Coopwood as Acting Executive Secretary. He also stated that Jeanne Mourrain was asked to remain as NELAC Director.

Ms. Nancy Wentworth, Director of EPA's Quality Assurance Division, stated that her division is interested in the quality of the entire measurement process, not just laboratory performance. She emphasized the comparability of proficiency testing data. She noted the need to work with mobile laboratories in addition to fixed analytical laboratories. Ms. Wentworth recognized that much of the "nuts and bolts" work of NELAC has been done by State agencies, and promised continued funding support so that NELAC can maintain forward progress.

Mr. Steve Clark, from EPA's Office of Water (OW), discussed the implementation of NELAC in the Office of Water. OW views NELAC as an "alternative guidance" for use by States in the certification of laboratories under the Safe Drinking Water Act. He reviewed the October 20, 1997, letter from OW to their Regional representatives and officers who had inquired about the relationship between OW and NELAP. This letter has been provided this week's conference participants in the front section of the three-ring binder.

Mr. Clark remarked that he is encouraged by "large" States (i.e., States with large populations, large cities, and the greatest risks to health) which have been among the first to participate in NELAC, but reminded all that NELAC is a voluntary program. He acknowledged differences between OW and NELAC on particular issues (e.g., frequency of PT samples). Mr. Clark also promised that OW will publish in a Federal Register notice to advise laboratories of the availability of NELAP as alternative guidance.

Dr. Ken Jackson, Chair-Elect, congratulated participants on progress to date, stating that he is excited that 17 States or more will be accredited authorities by the end of the year. He reminded all that the NELAC Standards are a "living" document. The implementation process will lead to further changes. Moving into implementation will require added cooperation between EPA, the States, and the private sector. Mr. Jackson thanked Ted Coopwood. He also stated that Jeanne Mourrain, more than anyone, has kept the program moving--toward resolution of issues of controversy. In closing, he announced that the NELAC Annual Meeting in the summer of 1999

will be in Saratoga Springs, NY. He closed by stating: “Next summer, implementation will be a reality.”

Dr. Charles Hartwig announced that nominees for the Board will be contacted before the Annual Meeting to verify their availability for service.

COMMITTEE WORKING SESSIONS

For two days following the opening plenary session, concurrent working sessions involving all 13 standing, administrative, and ad hoc committees were held. Progress made by each committee, as well as principal unresolved issues (and time frames for addressing them, if defined) are listed below. In keeping with the goals established for the Interim Meeting, all working sessions were of an open-forum format; a session typically included committee members, Federal and State representatives, as well as representatives from laboratories, accrediting organizations, industry and the general public.

Program Policy & Structure — The committee proposed the creation of a new standing committee called “Sampling & Field Measurements,” which would broaden the scope of NELAC beyond laboratories. Other proposed changes included a change in reporting intervals so that revisions and reports are available sooner; establishment of criteria to support creation of a new standing committee; and broadened responsibility of the NELAC Board to include assurance that the board and committees respond to constituent concerns and needs. Permissible use of the NELAC logo is being reviewed by US EPA legal counsel. It is unresolved whether or not to substitute other words for “reciprocity,” such as “recognition.” The committee intends to continue discussion on the issues of reciprocity with the Accrediting Authority Committee. The committee also intends to discuss issues of “rights of appeal” with the Accreditation Process Committee. All sections of Chapter 1 have been adopted and revisions to several sections are ready for voting.

Proficiency Testing — After consideration of comments and cooperative discussions with EPA/NIST regarding externalization, most revisions of Chapter 2 are ready for voting. Sections remaining for review include Appendices A-D and the new Appendix E (Microbiology Proficiency Testing). The committee intends to develop language on scheduling of PT rounds; further develop appendices on radiochemistry, biology (environmental toxicology), and air (Appendices F, G, and H, respectively); and consider details of EPA/NIST externalization process. Appendix H (Air) will need to be coordinated with the Field Measurements Committee. Future plans may include the development of additional appendices such as asbestos and solid waste.

On-site Assessment — Revisions to several sections are ready for voting. Future plans include: formation of a subcommittee to link the On-site Assessment and the Quality Systems Committees; development of quality system checklists; review of the existing training manual to ensure that the most recent redline corrections have been posted on the Web; incorporate Chapter 5 and Appendix D of Chapter 5 into existing method checklists; and review DOD comments from the July 1997 Annual Meeting. Unresolved issues include: the detachment of the training manual from the Chapter 3 standard; resources for specific committee tasks, such as training manual and

checklists; and clarification of roles and responsibilities regarding training of assessors. A checklist representative of the efforts of the Checklist Subcommittee will be posted on the Web for comment.

Accreditation Process — Revisions to several sections are ready for voting. In Section 4.1.1.1, “responsible party of record” was replaced with “technical director(s), however named” which eliminates the “assistant director” level. The issue on mobile labs was clarified in Section 4.1.2. One issue left unresolved was the guidelines for remote sites. The committee plans to incorporate the ramifications of changes made in other standards such as the effect of PT failure on accreditation status and the recertification process (this will be discussed with the PT Committee). Future plans also include preparation of an Appeals Process Statement and further review/clarification of suspension and revocation criteria.

Quality Systems — The committee reported that there were a few comments on the proposed revisions, but no major issues and no substantive modifications. All sections of Chapter 5 have been adopted and the revisions are ready for voting. However, the appendix covering Performance Based Measurement Systems (PBMS) is not ready to submit for voting. Program-specific requirements are also unresolved. The committee requested a single set of comments from EMMC on quality systems; this will be the focus of a late March meeting. The committee’s goals are to continue to clarify and refine the standards, ensuring audit ability and consistent application. Long-term plans for the committee include consideration of method detection limits (MDLs), data qualifiers, and calibration criteria.

Accrediting Authority — Proposed revisions to Section 6 include: revision to clarify the process for accreditation of laboratories operated by an accrediting authority; addition of two ISO requirements to the list of items to be included in an accrediting authority’s Quality Manual; and inclusion of a sunset clause to the provision that currently allows an accrediting authority making an initial application for NELAP recognition to have up to two years to correct legislative or rulemaking revisions to its program. The committee considered changing the term “reciprocity” to “recognition” throughout the NELAC standard, but the issue has been put on hold until further discussion by the board. The committee reported that all sections of Chapter 6 have been adopted, although some editorial changes will be made. Future plans include: review of the subcommittee report on ISO Requirements; review of training-requirement options for members of the NELAP Assessment Team; and proposed revisions to Chapter 6 ready for voting at NELAC IV.

Implementation — The results of a survey conducted by the National Conference of State Legislators (NCSL) were distributed and discussed. NCSL received a 40 percent response rate from the States and Territories (20 out of 52) and 17 percent from the individual legislators (29 out of 170) contacted. The committee plans to coordinate with the Membership and Outreach Committee to send fact sheets to non-respondents of the NCSL survey. The committee also intends to gather information on existing State certification programs that were not identified in the NCSL survey. Small laboratories comprise a large community of affected stakeholders, but many of them do not belong to trade associations or have the resources to attend NELAC meetings. The committee intends to develop a guidance document in order to educate and assist the small laboratory community in NELAC certification and its benefits. Plans also include the

development of a model Quality Systems document for small laboratories; two example Quality Assurance Plans that could be used as models were distributed. A cost/benefit analysis for the implementation of NELAC standards to accredited laboratories and State certification programs has been drafted; the committee plans to continue to research and revise the document, and distribute it for review and comment. Example preambles for State rulemaking packages (e.g., Statement of Purpose and Effect, Economic Impact Statement) and an analyte sheet consistent with NELAC tiers of accreditation were distributed; the committee intends to revise these documents per reviewer comments.

Conference Management — Dates and locations for upcoming meetings are as follows: the 1998 Annual Meeting will be held in San Antonio, Texas at the Omni Hotel; the 1998 Interim Meeting will be held in Washington, D.C. (first week of December); and the 1999 Annual Meeting will be held in Saratoga Springs, New York (last week of June). It was noted for future planning that the dates of the Annual Conference presents problems for some States due to the end of the fiscal year constraints. There was discussion about cosponsors and conference fees for both interim and Annual Meetings, however these issues have not been resolved.

Membership and Outreach — Committee discussions focusing on strategies for improving the NELAC Web site included: posting of fact sheets, impending operational changes to the Web site, possible restructuring of the access tree to information on the Web site, presentation formats for documents, and the need for a general overview and introduction to NELAC on the home page. Future plans of the committee include preparation of fact sheets for the NELAC Web page and distribution to the States; preparation of letters to Governors requesting appointment of State representatives; development of a procedure for checking voter credentials; development of a flow chart to delineate Membership and Outreach Committee versus NELAP roles in maintaining committee memberships and terms; and language for the by-laws regarding Membership and Outreach Committee duties (ready for vote in 1998).

Nominating — The Nominating Committee identified several potential nominees for members-at-large. It was agreed that there should be one state and one federal member-at-large to replace those rotating off the Board. Nominees were also identified for the position of chair-elect.

Transition — Seventeen States indicated they will submit applications to become accrediting authorities under NELAP by January 31, 1998. They are Arkansas, California, Colorado, Florida, Idaho, Illinois, Kansas, Nebraska, New Hampshire, New Jersey, New York, Ohio, Oregon, Pennsylvania, Texas, Utah, and Virginia. One State will submit applications for two accrediting authorities. These States currently employ 84 surveyors and accredit 3,401 in-state and 1,227 out-of-state laboratories. Ten States indicated they will submit applications by October 1998. Processing of applications will begin January 1, 1998.

The committee recommends that the NELAC Board of Directors adopt a resolution replacing the word “reciprocity” with “recognition.” The term “reciprocity” creates problems for some States because it carries a great deal of “legal baggage” that States will have to deal with. They also recommend that, within the context of NELAP, the term “non-NELAP” be applied to any state/federal accreditation program that is not NELAC-recognized. Unresolved issues include:

the use of supplemental State requirements; training of program and laboratory assessors; and schedule for recognition of accrediting authorities and laboratories.

Field Measurements — The establishment of a standing committee on Sampling and Field Measurements (S&FM) has been endorsed by the NELAC Board of Directors. The committee reviewed several documents: Navy standards and A2LA draft requirements, EPA Region 4's Standard Operating Procedures and Quality Assurance Manual, and EPA's "Accreditation and Qualification Criteria for Measurement of Emissions: AQME Program." The committee discussed outreach options, since the participation of potentially affected organizations, many of which are not currently represented at NELAC, is in question. This may be a deciding factor in whether to incorporate S&FM standards into existing chapters or to let it stand alone. The committee is trying to resolve how to structure the Field Standards, and plans to develop an options paper for the Board to review.

National Database — The committee considered both an interim and a long-term database. The Interim National Database can be implemented using a "Lotus Approach," would be resident on the EPA Web site, and would contain data on accrediting authorities only. This should be ready by the time the first round of accrediting authorities are accepted. Plans for the long-term National Database include: recruit an EPA technical member to the committee; collect information on user needs; specify database requirements; and generate a cost estimate. The committee does not yet have a chair; nominees will be contacted to see if they are willing serve.

CLOSING PLENARY SESSION

The closing plenary session of the Third NELAC Interim Meeting was convened by the NELAC Chair, Ms. Carol Batterton. The session began with each committee chair presenting a brief activity report for his or her group (see above). These committee summary reports included the highlights of discussions in the committee sessions, an itemization of unresolved issues, future plans, and timetables for completion of those plans. At the end of the session summaries, Ms. Batterton reminded attendees that additional comments should be submitted to committee chairs by January 15, 1998.

In her closing remarks, Ms. Batterton commented on the program-specific issues with the EPA's Office of Solid Waste. She noted that a NELAC delegation met with Mr. Tim Fields, Acting Administrator of OSWER to answer some of OSWER's questions about NELAC plans. In response, Mr. Fields offered his support to NELAC efforts. In conclusion, she thanked the board, committee chairs, and RTI for their efforts in ensuring the success of this Interim Meeting.

Ms. Jeanne Mourrain, NELAC Director, ended the session with her outline of the next steps. Before doing so, she introduced Ms. Carolyn Cross, who is the newest a member of the NELAP staff. Ms. Mourrain then reminded attendees of the conference evaluation form and the committee nomination form.

Ms. Mourrain stated that regarding the Standards, NELAC is going to be working with EMMC where there are issues related to EPA programs. NELAC will continue to work with NIST on

the externalization program. She reminded the audience that there will be a formal meeting for ELAB on January 16, 1998 (1 to 5 p.m.), followed by an open forum from 5 to 6 p.m. There will be a meeting with NIST January 16, 1998 from 8 a.m. to noon.

Ms. Mourrain noted that it is a goal to have an Accrediting Authority Review Board established within next couple of months to deal with problems in evaluating accrediting authorities. It will be comprised of State or Federal officials only.

ENVIRONMENTAL LABORATORY ADVISORY Board

The Environmental Laboratory Advisory Board (ELAB) met on Thursday, January 15, 1998. The meeting was led by its co-chairs, Dr. Wilson Hershey and Ms. Ramona Trovato. The following topics were brought forth by attendees: due process for laboratories, audit consistency, time limits for recognition of certified laboratories, rule enforcement, special treatment of small laboratories, expansion of NELAP into sampling and field measurements, and conflicts of interest between authorities assessing one another's programs. With respect to the conference, there was concern about lack of representation of sampling personnel at the NELAP and ELAB meetings. Attendees considered the separation of the ELAB meeting from future NELAP conferences to be a problem, and requested continuance of a close conjunction between the two meetings. The meeting was adjourned at 6 p.m.